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K033768

Attachment 17
510(k) Summary for the
Optional Infrared Handpiece

I. General Information

Submitter:	Altus Medical, Inc. 821 Cowan Road Burlingame, CA 94010
Contact Person:	Kathy Maynor
Telephone: Fax:	650-259-5586 650-552-9787
Summary Preparation Date:	November 18, 2003

II. Names

Device Proprietary Name:	Altus Medical Optional Infrared Handpiece
Primary Classification Name:	Infrared Lamp – product code 89 ILY; class II; 890.5500
Common Name:	Infrared lamp

III. Predicate Devices

- K001056 – Olympic Warm-up by Olympic Medical
- K022609 – PW820 Patient Warmer by Fisher & Paykel
- K023621 – BioFlex Professional Therapy System by Meditech International
- K024179 – Thermapulse by Palomar Medical Technologies, Inc.

IV. Product Description/Technological Characteristics

The optional infrared handpiece consists of:

- an "umbilical" cable and connector, that is permanently attached to the hand piece body and is semi-permanently attached to the laser system (detachable by positive action from the user) that houses:
- electrical cables (to support the thermoelectric coolers associated with the chilled sapphire window, to provide power and an electrical drive current to the IR quartz lamp, to provide detector signals and to connect a memory device that identifies the hand piece);
- a supply and return water line (to remove the heat generated by the infrared lamp and thermoelectric cooler);

- the hand piece internals described above; and
- the hand piece shells housing the internals and connecting to the umbilical.

The proximal end of the umbilical cable is semi-permanently attached to the laser system console and the distal end is permanently attached to the body of the delivery hand piece. This hand piece is removable by either the user or an authorized field service engineer for replacement at the proximal end.

This optional infrared handpiece is for use specifically with the Altus Medical CoolGlide Xeo laser system previously cleared on K023954.

V. Statement of Intended Use

The Altus Medical optional infrared handpiece is intended to emit energy in the infrared spectrum to provide topical heating for the purpose of elevating tissue temperature for the temporary relief of minor muscle and joint pain and stiffness, the temporary relief of minor joint pain associated with arthritis, the temporary increase in local circulation where applied, and the relaxation of muscles. In addition, the Altus Medical optional infrared handpiece may also help muscle spasms, minor sprains and strains, and minor muscular back pain.

VI. Rationale for Substantial Equivalence

The optional infrared handpiece shares the same general indications for use, and therefore is substantially equivalent to the currently marketed infrared heat lamps. The relevant technological characteristics of the Altus Medical optional infrared handpiece compared to the predicate devices include:

Lamp type: Equivalent to the Olympic Medical Warm-Up lamp from Olympic Medical
Timer: Equivalent to the Thermapulse device from Palomar Technologies
Total electrical wattage: Substantially equivalent to the Olympic Medical Warm-Up Lamp
Power: Equivalent to the Thermapulse device from Palomar Technologies
Wavelength: Substantially equivalent to the BioFlex Professional Therapy System from Meditech International and the PW820 Patient Warmer from Fisher & Paykel
Protective Enclosure: Equivalent to the Thermapulse from Palomar Technologies
Spot Size: Equivalent to the BioFlex Professional Therapy System from Meditech Interntional
Skin contact: Equivalent to the BioFlex Professional Therapy System
Cooling: Substantially equivalent to the PW820 Patient Warmer
Energy: Substantially equivalent to the Bioflex Professional Therapy System and the PW820 Patient Warmer

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Electrical Requirements: Equivalent to the PW820 Patient Warmer
Delivery device: Substantially equivalent to the Thermapulse and the BioFlex Professional Therapy System

VII. Safety and Effectiveness Information

Technologically, the optional infrared handpiece is substantially equivalent to the listed predicate devices. Therefore the risks and benefits for the CoolGlide optional infrared handpiece are comparable to the predicate devices.

We therefore believe that there are no new questions of safety or effectiveness raised by the introduction of this device.

VIII. Conclusion

The optional infrared handpiece was found to be substantially equivalent to the currently marketed infrared heat lamps. The optional infrared handpiece shares similar indications for use, design features, and similar functional features as, and thus are substantially equivalent to, the currently marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 17 2004

Altus Medical, Inc.
c/o Mr. Morten S. Christensen
Underwriters Laboratories, Inc.
1655 Scott Boulevard
Santa Clara, California 95050

Re: K033768
Trade/Device Name: Optional Infrared Handpiece for CoolGlide Lasers
Regulation Number: 21 CFR 890.5500
Regulation Name: Infrared lamp
Regulatory Class: II
Product Code: ILY
Dated: January 30, 2004
Received: February 2, 2004

Dear Mr. Christensen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Attachment 2
Indications For Use Statement as Requested by FDA

510(k) Number (if Known): K033768

Device Name: **Optional Infrared Handpiece for CoolGlide Lasers**

Indications For Use:

The Altus Medical optional infrared handpiece is intended to emit energy in the infrared spectrum to provide topical heating for the purpose of elevating tissue temperature for the temporary relief of minor muscle and joint pain and stiffness, the temporary relief of minor joint pain associated with arthritis, the temporary increase in local circulation where applied, and the relaxation of muscles. In addition, the Altus Medical optional infrared handpiece may also help muscle spasms, minor sprains and strains, and minor muscular back pain.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

Miriam C. Provost (Optional Format 1-2-96

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K033768